

Statement of Rep. Henry A. Waxman
Floor Consideration of H.R. 2900,
Food and Drug Administration Amendments Act of 2007
July 11, 2007

I rise in support of H.R. 2900, The Food and Drug Administration Amendments Act of 2007.

It has become increasingly clear over recent years that FDA needs more of two things: it needs more resources and it needs more authority. This is particularly true in the area of post-market drug safety. We are all familiar with the series of recent high-profile drug safety problems, with drugs like Vioxx and Avandia. It's no secret that FDA's ability to protect the safety of our drugs is in serious jeopardy.

H.R. 2900 makes significant strides in getting FDA both the authorities and resources to improve its oversight of drug safety.

I am pleased that the bill incorporates provisions from the Enhancing Drug Safety and Innovation Act of 2007 which I introduced along with Rep. Markey.

The Enhancing Drug Safety and Innovation Act of 2007—and now H.R. 2900—incorporates many of the recommendations made by the Institute of Medicine in its groundbreaking report on FDA's post-market drug safety programs. For example, it will give FDA the ability to require post-market studies and labeling changes, as well as the ability to impose significant civil monetary penalties to ensure that these things get done in an appropriate and timely way. Another section of the bill would establish mandatory clinical trial registry and results databases. This will bring much-needed transparency to the clinical trials conducted on our fellow citizens and will prevent drug and device companies from hiding negative trial results that cast their products in a negative light.

I do regret that one of the important recommendations made by the IOM was stripped from the Committee-reported bill: that Congress give FDA the authority to restrict direct-to-consumer advertising of new drugs with unknown safety risks. If a new drug is heavily marketed as a result of direct-to-consumer ads, and a serious risk does emerge, many people will have been unnecessarily exposed to the risk. The advertising campaign for Vioxx was a very unfortunate illustration of this reality.

Similarly, I regret that H.R. 2900 does not contain a provision to appropriately tailor the period of exclusivity that blockbuster drugs receive in exchange for conducting pediatric trials under the Best Pharmaceuticals for Children Act (BPCA). We all share the goal of ensuring that our children get the same benefit from FDA approved drugs and medical devices as adults. But we must make sure that American consumers are not paying an unjustified price tag for those tests.

Nonetheless the bill as a whole makes significant contributions to the work of FDA and deserves our support.

I do want to emphasize that FDA will need a significant influx of resources to do what we are asking them to do in this bill. Although H.R. 2900 gives FDA the enhanced ability to dedicate user fee dollars to these activities, it will be critical that Congress come forward with additional appropriated dollars. We simply have got to get FDA the funds it needs to do this job well.

Every day, Americans rely on FDA to protect them from dangerous medicines. Today we have the opportunity to take a critically important step toward ensuring that FDA can fulfill this mission.

I encourage members to support the bill.